UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: September 23, 2022

SUBJECT: Efficacy Review for Honey Cake,
EPA Reg. No. 777-RUG
Action Code Case: 00306445
E-submission No. 64649

FROM: Luisa C. Samalot-Freire, Microbiologist
Efficacy Branch
Antimicrobials Division (7510M)
Date Signed: September 23, 2022

THRU: Tajah Blackburn, Ph.D., Senior Scientist
Efficacy Branch
Antimicrobials Division (7510M)
Date Signed: September 23, 2022

TO: Stacey Grigsby (RM), PM 34
Regulatory Management Branch II
Antimicrobials Division (7510M)

APPLICANT: Reckitt Benckiser, LLC

Formulation from the Label:

Active Ingredient(s)	% by wt.
Dipropylene glycol	14.00%
Other Ingredients	86.00%
Total	100.00%

I. BACKGROUND

Product Description (as packaged, as applied): Ready-to-Use Spray

Submission type: New Registration

Currently registered efficacy claim(s): Not Applicable, products is a new registration

Requested action(s): New Registration for an air sanitizer and air treatment spray against bacteria and viruses, respectively.

Documents considered in this review:

- Cover letter from applicant to EPA dated 6/17/2022
- Proposed label dated 6/11/2021 (Version 9)
- Data Matrix (EPA Form 8570-35) dated 6/17/2022
- Eight efficacy studies (MRIDs 51890603, 51890604, 51890605, 51915103, 51915104, 51915105, 51932801, 51932802)
- Confidential Statement of Formula (EPA Form 8570-4) dated 6/11/2021 and updated on 4/15/2022
- Transmittal Document (MRID 51923800), dated 6/17/2022
- Protocol Review for 777PA9: Honey Cake Air Sanitization Efficacy Protocol Review, dated 03/08/2022 (E-submission 63770, Action Code Case: 00302989)

  Note: Multiple documents have been submitted for this new product registration. The documents listed and dated above correspond to the latest documents used for the generation of this efficacy review.

II. PROPOSED DIRECTIONS FOR USE

"**To kill Bacteria* and Viruses** P**†** **in the Air (and Eliminate Odors):** Shake well before each use. Close or cover all doors, windows, air vents and returns. Only the user should be present during use. Hold can upright and continuously spray for 30 seconds towards the center of room in a sweeping motion (back and forth) (left and right). Room size defined as (10ft x 10ft x 8ft)(800 sq ft.). **To kill bacteria*** after spraying (exit)(leave) room for 4 minutes. **To kill viruses** P**†** after spraying (exit)(leave) room for 12 minutes. After use, resume normal room ventilation including uncovering returns and vents. Rinse food contact surfaces with potable water after use. "

III. STUDY SUMMARIES

1.	**MRID**	51890603		
Study Objective		Indoor Air Sanitization of Spray Formulation – Bactericidal / Using an Aerobiology Chamber		
Testing Lab; Lab Study ID		CREM Co. Labs. / RB220115-SA-01		
Experimental Start Date		1/15/2022	**Study Completion Date:**	04/01/2022
Test organism(s) ☒ **1** ☐ **2** ☐ **3** ☐ **4+**		*Staphylococcus aureus* (ATCC 6538)		
Test Method		Air Sanitization using an Aerobiology Chamber		
Application Method		Test substance (pressurized aerosol can) sprayed (released) for 30 seconds into chamber in a sweeping motion towards the chamber's ceiling after test microbe nebulization for 10 minutes.		

Test Substance Preparation	**Name/ID**	Lysol Neutra Air: Air Sanitizing Spray (FMLA# e0032-169)
	Lots ☒ **1** ☐ **2** ☐ **3**	e0199-069
	Preparation	Tested concentration: LCL Tested Dilution: Not applicable – product is a Ready-to-Use Spray Diluent: Not Applicable
Soil load		5% three-part soil (a mixture of bovine mucin, bovine serum albumin, and yeast extract)
Carrier type, # per lot		Aerobiology Chamber – 900 ft^3 or 25 M^3
Test conditions		Contact time: 3.46 minutes Temperature: 20-25°C Relative humidity: 50±5%
Neutralizer		TSAM (TSA + 0.07% Lecithin + 0.5% Tween 80 + 0.02% Sodium Thiosulfate)
Incubation conditions		Sampling plates were first observed at 18±2 hours of incubation, final results were collected after 3 days of additional incubation. All plates were incubated at 36±1°C.
Reviewer comments (i.e., protocol deviations and amendments, retesting, control failures, etc.)		Study was conducted as per protocol 777- PA9, protocol review dated 3/8/2022. Efficacy test dates = 1/28/22, 1/31/22 and 2/2/22. A unique aerosol can was assigned to each test date. Three untreaded control tests were performed on the test microbe to determine its rate of biological decay in the chamber prior to efficacy testing. Protocol amendments and Deviations are presented on Appendix D pages 44-59.

2.	**MRID**	51890604		
Study Objective		Indoor Air Sanitization of Spray Formulation – Bactericidal / Using an Aerobiology Chamber		
Testing Lab; Lab Study ID		CREM Co. Labs. / RB220115-SA-02		
Experimental Start Date		1/15/2022	**Study Completion Date:**	04/01/2022
Test organism(s) ☒ **1** ☐ **2** ☐ **3** ☐ **4+**		*Staphylococcus aureus* (ATCC 6538)		
Test Method		Air Sanitization using an Aerobiology Chamber		
Application Method		Test substance (pressurized aerosol can) sprayed (released) for 30 seconds into chamber in a sweeping motion towards the chamber's ceiling after test microbe nebulization for 10 minutes.		
Test Substance Preparation	**Name/ID**	Lysol Neutra Air: Air Sanitizing Spray (FMLA# e0032-169)		
	Lots ☒ **1** ☐ **2** ☐ **3**	e0032-170		
	Preparation	Tested concentration: LCL Tested Dilution: Not applicable – product is a Ready-to-Use Spray Diluent: Not Applicable		
Soil load		5% three-part soil (a mixture of bovine mucin, bovine serum albumin, and yeast extract)		

Carrier type, # per lot	Aerobiology Chamber – 900 ft^3 or 25 M^3
Test conditions	Contact time: 3.30 minutes Temperature: 20-25°C Relative humidity: 50±5%
Neutralizer	TSAM (TSA + 0.07% Lecithin + 0.5% Tween 80 + 0.02% Sodium Thiosulfate)
Incubation conditions	Sampling plates were first observed at 18±2 hours of incubation, final results were collected after 3 days of additional incubation. All plates were incubated at 36±1°C.
Reviewer comments (i.e., protocol deviations and amendments, retesting, control failures, etc.)	Study was conducted as per protocol 777- PA9, protocol review dated 3/8/2022. Efficacy test dates = 2/3/22, 2/4/22 and 2/7/22. A unique aerosol can was assigned to each test date. Three untreaded control tests were performed on the test microbe to determine its rate of biological decay in the chamber prior to efficacy testing. Protocol amendments and Deviations are presented on Appendix D pages 44-52.

3.	**MRID**	51890605		
Study Objective		Indoor Air Sanitization of Spray Formulation – Bactericidal / Using an Aerobiology Chamber		
Testing Lab; Lab Study ID		CREM Co. Labs. / RB220115-SA-03		
Experimental Start Date		1/15/2022	**Study Completion Date:**	03/28/2022
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Staphylococcus aureus* (ATCC 6538)		
Test Method		Air Sanitization using an Aerobiology Chamber		
Application Method		Test substance (pressurized aerosol can) sprayed (released) for 30 seconds into chamber in a sweeping motion towards the chamber's ceiling after test microbe nebulization for 10 minutes.		
Test Substance Preparation	**Name/ID**	Lysol Neutra Air: Air Sanitizing Spray (FMLA# e0032-169)		
	Lots **☒ 1 ☐ 2 ☐ 3**	e0199-070		
	Preparation	Tested concentration: LCL Tested Dilution: Not applicable – product is a Ready-to-Use Spray Diluent: Not Applicable		
Soil load		5% three-part soil (a mixture of bovine mucin, bovine serum albumin, and yeast extract)		
Carrier type, # per lot		Aerobiology Chamber – 900 ft^3 or 25 M^3		
Test conditions		Contact time: 2.86 minutes Temperature: 20-25°C Relative humidity: 50±5%		
Neutralizer		TSAM (TSA + 0.07% Lecithin + 0.5% Tween 80 + 0.02% Sodium Thiosulfate)		
Incubation conditions		Sampling plates were first observed at 18±2 hours of incubation, final results were collected after 3 days of additional incubation. All plates were incubated at 36±1°C.		

Reviewer comments (i.e., protocol deviations and amendments, retesting, control failures, etc.)	Study was conducted as per protocol 777- PA9, protocol review dated 3/8/2022. Efficacy test dates = 2/8/22, 2/9/22 and 2/10/22. A unique aerosol can was assigned to each test date. Three untreaded control tests were performed on the test microbe to determine its rate of biological decay in the chamber prior to efficacy testing. Protocol amendments and Deviations are presented on Appendix D pages 44-52.

4.	**MRID**	51915103		
Study Objective		Indoor Air Sanitization of Spray Formulation – Bactericidal / Using an Aerobiology Chamber		
Testing Lab; Lab Study ID		CREM Co. Labs. / RB220115-KN-01		
Experimental Start Date		1/15/2022	**Study Completion Date:**	04/03/2022
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Klebsiella pneumoniae* (ATCC 4352)		
Test Method		Air Sanitization using an Aerobiology Chamber		
Application Method		Test substance (pressurized aerosol can) sprayed (released) for 30 seconds into chamber in a sweeping motion towards the chamber's ceiling after test microbe nebulization for 10 minutes.		
Test Substance Preparation	**Name/ID**	Lysol Neutra Air: Air Sanitizing Spray (FMLA# e0032-169)		
	Lots **☒ 1 ☐ 2 ☐ 3**	e0199-069		
	Preparation	Tested concentration: LCL Tested Dilution: Not applicable – product is a Ready-to-Use Spray Diluent: Not Applicable		
Soil load		5% three-part soil (a mixture of bovine mucin, bovine serum albumin, and yeast extract)		
Carrier type, # per lot		Aerobiology Chamber – 900 ft^3 or 25 M^3		
Test conditions		Contact time: 1.17 minutes Temperature: 20-25°C Relative humidity: 50±5%		
Neutralizer		TSAM (TSA + 0.07% Lecithin + 0.5% Tween 80 + 0.02% Sodium Thiosulfate)		
Incubation conditions		Sampling plates were first observed at 18±2 hours of incubation, final results were collected after 3 days of additional incubation. All plates were incubated at 36±1°C.		
Reviewer comments (i.e., protocol deviations and amendments, retesting, control failures, etc.)		Study was conducted as per protocol 777- PA9, protocol review dated 3/8/2022. Efficacy test dates = 3/3/22, 3/7/22 and 3/9/22. A unique aerosol can was assigned to each test date. Three untreaded control tests were performed on the test microbe to determine its rate of biological decay in the chamber prior to efficacy testing.		

	Protocol amendments and Deviations are presented on Appendix D pages 45-62.

5.	**MRID**	51915104		
Study Objective		Indoor Air Sanitization of Spray Formulation – Bactericidal / Using an Aerobiology Chamber		
Testing Lab; Lab Study ID		CREM Co. Labs. / RB220115-KN-02		
Experimental Start Date		1/16/2022	**Study Completion Date:**	04/03/2022
Test organism(s) ☒ **1** ☐ **2** ☐ **3** ☐ **4+**		*Klebsiella pneumoniae* (ATCC 4352)		
Test Method		Air Sanitization using an Aerobiology Chamber		
Application Method		Test substance (pressurized aerosol can) sprayed (released) for 30 seconds into chamber in a sweeping motion towards the chamber's ceiling after test microbe nebulization for 10 minutes.		
Test Substance Preparation	**Name/ID**	Lysol Neutra Air: Air Sanitizing Spray (FMLA# e0032-169)		
	Lots ☒ **1** ☐ **2** ☐ **3**	e0032-170		
	Preparation	Tested concentration: LCL Tested Dilution: Not applicable – product is a Ready-to-Use Spray Diluent: Not Applicable		
Soil load		5% three-part soil (a mixture of bovine mucin, bovine serum albumin, and yeast extract)		
Carrier type, # per lot		Aerobiology Chamber – 900 ft^3 or 25 M^3		
Test conditions		Contact time: 1.12 minutes Temperature: 20-25°C Relative humidity: 50±5%		
Neutralizer		TSAM (TSA + 0.07% Lecithin + 0.5% Tween 80 + 0.02% Sodium Thiosulfate)		
Incubation conditions		Sampling plates were first observed at 18±2 hours of incubation, final results were collected after 3 days of additional incubation. All plates were incubated at 36±1°C.		
Reviewer comments (i.e., protocol deviations and amendments, retesting, control failures, etc.)		Study was conducted as per protocol 777- PA9, protocol review dated 3/8/2022. Efficacy test dates = 3/10/22, 3/12/22 and 3/14/22. A unique aerosol can was assigned to each test date. Three untreaded control tests were performed on the test microbe to determine its rate of biological decay in the chamber prior to efficacy testing. Protocol amendments and Deviations are presented on Appendix D pages 45-58.		

6.	**MRID**	51915105		
Study Objective		Indoor Air Sanitization of Spray Formulation – Bactericidal / Using an Aerobiology Chamber		
Testing Lab; Lab Study ID		CREM Co. Labs. / RB220115-KN-03		
Experimental Start Date		1/16/2022	**Study Completion Date:**	04/30/2022

Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Klebsiella pneumoniae* (ATCC 4352)
Test Method		Air Sanitization using an Aerobiology Chamber
Application Method		Test substance (pressurized aerosol can) sprayed (released) for 30 seconds into chamber in a sweeping motion towards the chamber's ceiling after test microbe nebulization for 10 minutes.
Test Substance Preparation	**Name/ID**	Lysol Neutra Air: Air Sanitizing Spray (FMLA# e0032-169)
	Lots **☒ 1 ☐ 2 ☐ 3**	e0199-070
	Preparation	Tested concentration: LCL Tested Dilution: Not applicable – product is a Ready-to-Use Spray Diluent: Not Applicable
Soil load		5% three-part soil (a mixture of bovine mucin, bovine serum albumin, and yeast extract)
Carrier type, # per lot		Aerobiology Chamber – 900 ft^3 or 25 M^3
Test conditions		Contact time: 1.16 minutes Temperature: 20-25°C Relative humidity: 50±5%
Neutralizer		TSAM (TSA + 0.07% Lecithin + 0.5% Tween 80 + 0.02% Sodium Thiosulfate)
Incubation conditions		Sampling plates were first observed at 18±2 hours of incubation, final results were collected after 3 days of additional incubation. All plates were incubated at 36±1°C.
Reviewer comments (i.e., protocol deviations and amendments, retesting, control failures, etc.)		Study was conducted as per protocol 777- PA9, protocol review dated 3/8/2022. Efficacy test dates = 3/16/22, 3/17/22 and 3/19/22. A unique aerosol can was assigned to each test date. Three untreaded control tests were performed on the test microbe to determine its rate of biological decay in the chamber prior to efficacy testing. Protocol amendments and Deviations are presented on Appendix D pages 45-58.

7.	**MRID**	51932801		
Study Objective		Indoor Air Sanitization of Spray Formulation –Virucidal / Using an Aerobiology Chamber		
Testing Lab; Lab Study ID		CREM Co. Labs. / RB220115-MS2-01		
Experimental Start Date		1/26/2022	**Study Completion Date:**	5/27/2022
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Coliphage MS-2 (ATCC 15597-B1) with host *Escherichia coli* (ATCC 15597)		
Indicator Cell Culture		Host cell = *Escherichia coli* (ATCC 15597)		
Test Method		Air Sanitization using an Aerobiology Chamber		
Application Method		Test substance (pressurized aerosol can) sprayed (released) for 30 seconds into chamber in a sweeping motion towards the chamber's ceiling after test microbe nebulization for 10 minutes.		
	Name/ID	Lysol Neutra Air: Air Sanitizing Spray (FMLA# e0032-169)		

Test Substance Preparation	**Lots** ☒ 1 ☐ 2 ☐ 3	e0199-069
	Preparation	Tested concentration: LCL Tested Dilution: Not applicable – product is a Ready-to-Use Spray Diluent: Not Applicable
Soil load		5% three-part soil (a mixture of bovine mucin, bovine serum albumin, and yeast extract)
Carrier type, # per lot		Aerobiology Chamber – 900 ft^3 or 25 M^3
Test conditions		Contact time: 11.3 minutes Temperature: 20-25°C Relative humidity: 50±10%
Neutralizer		LMB Agar (LB agar + 0.07% Lecithin + 0.5% Tween 80)
Incubation conditions		Plates incubated at 36±1ºC – observed after 18±2 hours and continued incubation for an additional 3 days prior to determining final counts.
Reviewer comments (i.e., protocol deviations and amendments, retesting, control failures, etc.)		Study was conducted as per protocol 777- PA9, protocol review dated 3/8/2022. Efficacy test dates = 5/2/22, 5/3/22 and 5/4/22. Three untreaded control tests were performed on the test microbe to determine its rate of biological decay in the chamber prior to efficacy testing. Note from reviewer: for bactericidal tests – under Section: Efficacy Test with Test Substance, there is an indication of the number of cans used per test dates. This information was not provided for the virucidal studies. Protocol amendments and Deviations are presented on Appendix D pages 44-58.

8.	**MRID**	51932801		
Study Objective		Indoor Air Sanitization of Spray Formulation –Virucidal / Using an Aerobiology Chamber		
Testing Lab; Lab Study ID		CREM Co. Labs. / RB220115-MS2-01		
Experimental Start Date		1/26/2022	**Study Completion Date:**	5/27/2022
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Coliphage MS-2 (ATCC 15597-B1) with host *Escherichia coli* (ATCC 15597)		
Indicator Cell Culture		Host cell = *Escherichia coli* (ATCC 15597)		
Test Method		Air Sanitization using an Aerobiology Chamber		
Application Method		Test substance (pressurized aerosol can) sprayed (released) for 30 seconds into chamber in a sweeping motion towards the chamber's ceiling after test microbe nebulization for 10 minutes.		
Test Substance Preparation	**Name/ID**	Lysol Neutra Air: Air Sanitizing Spray (FMLA# e0032-169)		
	Lots ☒ 1 ☐ 2 ☐ 3	e0032-170		

	Preparation	Tested concentration: LCL Tested Dilution: Not applicable – product is a Ready-to-Use Spray Diluent: Not Applicable
Soil load		5% three-part soil (a mixture of bovine mucin, bovine serum albumin, and yeast extract)
Carrier type, # per lot		Aerobiology Chamber – 900 ft^3 or 25 M^3
Test conditions		Contact time: 9.8 minutes Temperature: 20-25°C Relative humidity: 50±10%
Neutralizer		LMB Agar (LB agar + 0.07% Lecithin + 0.5% Tween 80)
Incubation conditions		Plates incubated at 36±1ºC – observed after 18±2 hours and continued incubation for an additional 3 days prior to determining final counts.
Reviewer comments (i.e., protocol deviations and amendments, retesting, control failures, etc.)		Study was conducted as per protocol 777- PA9, protocol review dated 3/8/2022. Efficacy test dates = 5/21/22, 5/22/22 and 5/23/22. Three untreaded control tests were performed on the test microbe to determine its rate of biological decay in the chamber prior to efficacy testing. Note from reviewer: for bactericidal tests – under Section: Efficacy Test with Test Substance, there is an indication of the number of cans used per test dates. This information was not provided for the virucidal studies. Protocol amendments and Deviations are presented on Appendix D pages 44-56.

IV. STUDY RESULTS

Bactericidal Efficacy – Air Sanitization								
MRID	**Organism**	**Test Date**	**Efficacy and Control Results**					Untreated Controls (Average of three control tests) log_{10} CFU/m^3 – From time 0 – Time 20 of sampling)
			Bacterial Titer in Chamber after Nebulization (log_{10} CFU/m^3)	Log Reduction at end of sampling	Total sampling time (minutes)	Control Test Dates	Control Estimated Baseline Concentration from Nebulizer Fluid (log_{10} CFU/m^3)	
Ready-to-use spray, sprayed into an aerobiology chamber, 5% organic soil, 4 min contact time								
51990603	*Staphylococcus aureus* ATCC 6538	**Batch – e0199-069**						4.33-4.43 (Test dates: 1/21/22, 1/24/22, 2/17/22)
		1/28/22	4.28	≥3.0	3.46	1/21/22	4.31	
		1/31/22	4.21			1/24/22	4.36	
		2/2/22	4.30			2/17/22	4.34	
		Batch – e0032-170						
51990604		2/3/22	4.35	≥3.0	3.30	1/21/22	4.31	
		2/4/22	4.30			1/28/22	4.36	
		2/7/22	4.34			2/17/22	4.34	
		Batch – e0199-070						
51990605		2/8/22	4.21	≥3.0	2.86	1/21/22	4.31	
		2/9/22	4.30			1/28/22	4.36	
		2/10/22	4.22			2/17/22	4.34	

Bactericidal Efficacy – Air Sanitization								
MRID	**Organism**	**Test Date**	**Efficacy and Control Results**					Untreated Controls (Average of three control tests) log_{10} CFU/m^3 – From time 0 – Time 20 of sampling)
			Bacterial Titer in Chamber after Nebulization (log_{10} CFU/m^3)	Log Reduction at end of sampling	Total sampling time (minutes)	Control Test Dates	Control Estimated Baseline Concentration from Nebulizer	

							Fluid (log_{10} CFU/$m^{3)}$	
Ready-to-use spray, sprayed into an aerobiology chamber, 5% organic soil, 4 min contact time								
51915103	*Klebsiella pneumoniae* ATCC 4532	**Batch – e0199-069**						
		3/3/22	5.82	≥3.0	1.17	2/28/22	5.85	4.05-4.44 (Test dates: 2/28/22, 3/2/22, 3/21/22)
		3/7/22	5.60			3/2//22	5.92	
		3/9/22	5.78			3/21/22	5.92	
		Batch – e0032-170						
51915104		3/10/22	5.92	≥3.0	1.12	2/28/22	5.85	
		3/12/22	5.78			3/2//22	5.92	
		3/14/22	5.91			3/21/22	5.92	
		Batch – e0199-069						
51915105		3/16/22	5.86	≥3.0	1.16	2/28/22	5.85	
		3/17/22	5.86			3/2//22	5.92	
		3/19/22	5.80			3/21/22	5.92	

Virucidal Efficacy – Air Treatment								
MRID	**Organism**	**Test Date**	**Efficacy and Control Results**					Untreated Controls (Average of three control tests) log_{10} CFU/m^3 – From time 0 – Time 20 of sampling)
			Bacterial Titer in Chamber after Nebulization (log_{10} CFU/m^3)	Log Reduction at end of sampling	Total sampling time (minutes)	Control Test Dates	Control Estimated Baseline Concentration from Nebulizer Fluid (log_{10} PFU/$m^{3)}$	
Ready-to-use spray, sprayed into an aerobiology chamber, 5% soil load,12-minute contact time								
51932801	Coliphage MS-2 (ATCC 15597-B1) as a surrogate	**Batch – e0199-069**						4.04-4.36 (Test dates: 4/5/22, 4/8/22, 5/25/22)
		5/2/22	5.32	≥3.0	11.3	4/5/22	5.58	
		5/3/22	5.07			4/8/22	5.92	
		5/4/22	5.39			5/25/22	5.12	
51932802		**Batch – e0032-170**						
		5/21/22	5.22	≥3.0	9.80	4/5/22	5.58	
		5/22/22	5.30			4/8/22	5.92	
		5/23/22	5.19			5/25/22	5.12	

V. STUDY CONCLUSIONS

MRID	Claim	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
51990603 51990604 51990605	Air Sanitizer	Ready-to-Use Aerosol Spray	4 min	5%*	N/A**	S*taphylococcus aureus* (ATCC 6538)	**Yes**
51915103 51915104 51915105	Air Sanitizer	Ready-to-Use Aerosol Spray	4 min	5%*	N/A**	*Klebsiella pneumoniae* (ATCC 4532)	**Yes**
51932801 51932802	Air Treatment	Ready-to-Use Aerosol Spray	12 min	5%*	N/A**	Coliphage MS-2 (ATCC 15597-B1) as a surrogate	**Yes**

*three-part soil containing: a mixture of bovine mucin, bovine serum albumin, and yeast extract

**N/A=not applicable

VI. LABEL COMMENTS

Label Date/Identification Number: 6/10/2021 (version 9)

1. The proposed label claims that the product, Honey Cake, when used according to the Use Directions as a Ready-to-Use aerosol spray, is an effective **air sanitizer** against the following on room sizes defined as 10 ft x 10 ft x 8 ft or 800 sq. ft for a **4-minute** contact time:

   Staphylococcus aureus (ATCC 6538)
   Klebsiella pneumoniae (ATCC 4532)

   These claims are **acceptable** as they are supported by the submitted data.

2. The proposed label claims that the product, Honey Cake, when used according to the Use Directions as a Ready-to-Use aerosol spray, is an effective **air treatment** against the following on room sizes defined as 10 ft x 10 ft x 8 ft or 800 sq. ft for a **12-minute** contact time:

   Coliphage MS-2 (ATCC 15597-B1) as a surrogate for enveloped and non-enveloped airborne viruses in the air.

   These claims are **acceptable** as they are supported by the submitted data.

3. Make the following changes to the proposed label:
   a. Throughout the label
      i. Recommend removal of excess parenthesis for ease of review on the master label.
      ii. Revise or remove language such as antibacterial and antiviral as these terms correspond to FDA uses rather than EPAs. Consider using virucidal or bactericidal instead.
      iii. Remove references to “fight”, “fights” or “fights the spread of” where related to bacteria or viruses as this may be misleading to end users regarding the activity of the product.
   b. On page 2, remove language such as: “advanced technology, improved technology”, etc., as this language may indicate heightened efficacy.
      i. Remove language: “Freshness (Booster) (Enhancer)”, as this may indicate heightened efficacy.
      ii. Remove language: “Ordinary surface disinfectants or air fresheners can’t kill airborne microbes(?)”, this is a broad statement and comparative language that does not add to the product’s intended to use and it can be confusing to the user.
   c. On pages 2, 6, and 8, claims pertaining to “reducing the spread” of bacteria and viruses should specify “in the air” and “between treated spaces”
   d. On page 5:

i. Under General – Air Sanitization / Viral Air Treatment Claims – remove or qualify language "(eliminates)" from this statement: (3 in 1) (:) (eliminates)(removes)(neutralizes) odors (,) anti-bacterial* (&) (and) anti-viral† (air treatment) – as the term eliminates implies complete kill. This product is an air sanitizer and air treatment, and it does not kill all test microbes.

ii. Similarly, qualify "Eliminates (bacteria*), (,) (and) (&) (viruses†) (odors (*) (1)) (in air)" as this implies complete kill.

e. On page 6,

i. remove or qualify "(all over your) (home)(house)" to specify "in the air"

ii. remove parenthesis from "99.9% of" in "Molecules eliminate (99.9% of) (bacteria*) (and / &) (viruses†) in the air"

iii. qualify 'eliminator" in "Virus† (killer) (destroyer) (eliminator)" to specify 99.9%.

f. On page 6 Under Use Directions:

i. Add language in bold regarding room size to say: Room size defined as (10ft x 10ft x 8ft) (800 sq ft.). **For use in 800 sq ft or smaller rooms only.**

ii. Add language in bold regarding surfaces to be treated: Rinse food contact surfaces with potable water after use. **Product not intended to treat surfaces (hard or soft).**

iii. Revise language: Hold can upright and continuously spray for 30 seconds towards the center of room in a sweeping motion (back and forth) (left and right) – to say: Hold can upright and continuously spray for 30 seconds towards the center **and ceiling** of room in a sweeping motion (back and forth) (left and right). Avoid as much dermal and inhalation exposure as possible by spraying away from face.

iv. Add qualifier next to the word Bacteria on this statement: "To kill **Bacteria** and Viruses † in the Air".

v. Recommend adding "Ensure the room remains unoccupied for the duration of the contact time."

vi. Move language form Advisory Statement to Use Directions: "Not for use around food".

g. On page 6, under Optional Advisory Statements:

i. Revise language: For use 5 times a day" to say – For use up to 5 times a day per user".

ii. The Note to Reviewer for "Do not use more than 1 can a day" should be associated with a maximum packaging size/volume.

h. On page 8, graphics indicating "molecules eliminate bacteria/virus" should be revised to specify 99.9%. In addition, bacteria, and virus in each should be qualified to link to the tested organisms.

i. On page 9, "surrogate for rhinovirus, influenza virus, SARS-CoV-2 etc." should be revised to "surrogate for enveloped airborne viruses".

4. The following information should be included with the use directions on the proposed label to provide the proper context for the product's performance:

   "This product is not to be relied upon as the sole air treatment but as a supplement to be used in conjunction with current public health guidelines regarding filter ratings, HVAC system cleaning/maintenance, and the recommended number of air changes/per hour. This product has no residual efficacy at the conclusion of the contact time when the room is reoccupied, vents are returned to operation, and/or windows are opened.

Notes for RM/PM:

- In general, verify alternate brand names are appropriate.
- On page 4, ensure language about bleach, dyes, bleach free and phosphates are acceptable. In the case of bleach or bleach free language verify the language is appropriately linked to fabrics or garments.
- On page 4, ensure language such as: "No (harsh) (chemical) (smell) (and / or) (residues)(fumes)", as this can be misleading and comparative language in relation to other types of chemicals – is acceptable.
- On page 6, suggest removing parenthesis from language: (To Unlock Cap: Turn counterclockwise (1) (2) (clicks). Lock cap, after use.). Directions for use should not have optional language and should be clear to the user. Seems confusing to say 1 or 2 clicks, is the product unlocked with 1 or 2 counterclockwise clicks?
- On page 6, suggest clarification on how the user will avoid spraying in eyes, on skin or on clothing if they are in the room spraying the product. Language under Use Directions saying to spray in an upright position away from body may be necessary.
- On page 10, ensure language regarding (harsh acids) and chlorine bleach is acceptable.
- Verify that language on pages 4, and 6: "(Active) molecules kill (the)bacteria…", "The active molecules attach to the airborne bacteria (and / &) (viruses)", "Proprietary formula with active molecules", and "Proprietary formula with active molecules proven effective…" is allowed and not associated with nano particles.